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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,644	11/01/2001	Jean-Louis Bessereau	1321.2.28.1	7271

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/980,644	Applicant(s) BESSEREAU ET AL.	
	Examiner Scott D. Priebe, Ph.D.	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 Mar. & 27 Jun. 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,35,36,68-101 and 127-150 is/are pending in the application.
- 4a) Of the above claim(s) 68-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,35,36,127-135 and 139-150 is/are rejected.
- 7) ☒ Claim(s) 136-138 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20050627</u> . | 6) <input type="checkbox"/> Other: _____ |

5.00

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DETAILED ACTION

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1633 (formerly of GAU 1632).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 20, 35 and 36 under 35 USC 103(a) is hereby withdrawn. First, it is noted that the claims are not limited to germ line mutagenesis. However, none of the references cited in the rejection suggests or would placing the transposase under control of a 3' UTR from a gene expressed in *C. elegans* germ line in order to express the transposase in somatic cells. Neither does the cited art suggest modifying a transposase gene construct by inclusion of such a 3' UTR for some other reason, e.g. to promote germ line expression of the transposase. None of the references suggests such a modification. Van Leunen (1993) appears to be the closest prior art, but as pointed out by Applicant in the reply of 9/10/04 (pages 16-17), this reference taught that the heat shock promoter alone resulted in somatic cell transposition, not germ line transposition. Van Leunen (1993) teaches (page 2518) that one obtains germ line transposition when the nematode is in a mutator background, which for Tc3 is a mut-2 background. There is no suggestion here that one link the transposase gene to a 3' UTR of a gene expressed in *C. elegans* germ line. Gallegos et al. is a study of the control of *fem-3* expression by its 3' UTR. Also, Gallegos does not teach that the *fem-3* 3' UTR permits expression in germ line cells, so it is unclear whether the *fem-3* 3' UTR even meets the claim limitation. Gallegos does

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not make any suggestions as to whether this 3' UTR could be used for any practical purpose, much less using it to regulate expression of a transposase gene.

Specification

The amendment filed 6/27/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

SEQ ID NOs: 24-35 newly submitted in the Sequence Listing filed 6/27/05 and the references to these newly submitted sequences in the amendments to the paragraphs to replace the paragraphs beginning at page 5, line 16; beginning at page 6, line 21; page 11, line 19; and page 20, line 32, include material that is not supported by the original disclosure.

SEQ ID NOs: 24 and 25 are alleged to be the nucleotide sequence of the *Mos1* gene and the amino acid sequence of the transposase encoded thereby. In support of this newly added subject matter, Applicant simply states that these sequences were known in the art. In response, Applicant has provided no evidence that these sequences were known in the prior art, but in any case, whether these specific sequences were known in the prior art is irrelevant. Applicant has not indicated where the original disclosure supports these specific sequences, nor has Applicant provided any evidence that these specific sequences were inherent to any material that is disclosed in the specification, or were known to Applicant at the time the application was filed, or had been contemplated as being part of the original disclosure.

SEQ ID NOs: 26-34 appear to be nucleotide sequences that comprise at their 5' and 3' ends the paired nucleotide sequences shown on each successive line of Fig. 7C, and SEQ ID NO: 35 appears to be a nucleotide sequence that comprises at its 5' and 3' end the paired nucleotide sequences shown on page 32, line 21. Each of SEQ ID NOs: 26-35 contains considerable sequence information that was not provided in the original application, presumably intervening sequences that were omitted from the original disclosure. Applicant has not provided any explanation of the added sequence information and has not explained how the original disclosure supports the added sequence information, or provided any evidence that the new sequence information was contemplated as being part of the original application..

Applicant is required to cancel the new matter in the reply to this Office Action. A substitute Sequence Listing should be provided that lacks the sequences presented as SEQ ID NOs: 24-35. However, the new Sequence Listing and specification must comply with 37 CFR 1.821-1.825 (see PTO-90C filed 6/8/05). Applicant should provide a substitute paper copy of the 'Sequence Listing' and an amendment directing its entry into the specification, a substitute CRF of the 'Sequence Listing', and a statement that the content of the initial paper copy and the substitute CRF are the same, and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 37 CFR 1.821(f), 37 CFR 1.821(g), 37 CFR 1.825(b), or 37 CFR 1.825(d).

With respect to the nucleotide and amino acid sequences shown in Fig. 5A, each of the two oligopeptide sequences of four or more amino acids, and each of the three nucleotide sequences on next line should be added to the Sequence Listing, and their assigned SEQ ID NOs should be included in the 'Brief Description' of Fig. 5A in place of the added text referring to

SEQ ID NOs: 24 and 25. The reference to SEQ ID NOs: 24 and 25 in the paragraph on page 11, starting at line 19, should be deleted.

With respect to the 18 nucleotide sequences (9 paired sequence) shown in Fig 7C, each of the 18 sequences should be assigned its own SEQ ID NO, which should be included in the 'Brief Description' of Fig. 7C in place of the added text referring to SEQ ID NOs: 26-34. With respect to page 32, line 21, each of the two nucleotide sequences should be assigned a SEQ ID NO, both of which should be referred to in place of "SEQ ID NO: 35".

Claim Objections

Claims 35, 36, 127, 128, and 141 are objected to because of the following informalities. Claim 20 recites "a transposon" not "transposons." Consequently, "the transposons" in claims 35, 36 should be replaced with --the transposon--. Likewise, other appearances of "transposons" should be replaced with --transposon--, such as in "Tc3 transposons" in claim 128 and "*Mos 1* transposons" in claim 141. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 20, 35, and 36 remain rejected and claims 127-135 and 139-150 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record applied to claims 20-46 in the Office action of 2/25/04. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant's arguments filed 3/30/05 have been fully considered but they are not persuasive. Applicant argues that "the representative 3' UTRs used in the experiments ... are representative of the entire genus." However, the specification describes only one 3' UTR readable on the claims. Applicant has argued (reply filed 9/10/04) that the specification describes use of the 3' UTR of Tc3 and HIMAR1. The specification does not mention either of these 3' UTRs or teach that they are suitable for use in the claimed invention. The claims limit the 3' UTR to one from a *C. elegans* gene that is expressed in the germ line. As near as the Examiner can determine, the TC3A transposase is not normally expressed in germ line cells, which is one reason for the present invention, and the gene encoding HIMAR1 is not a *C. elegans* gene, this transposase is not from a transposon endogenous to *C. elegans*. Applicant argues that the basic functional features of a 3' UTR are known in the art, citing Pesole et al. and Jareborg et al. In response, neither of these mention 3' UTRs of any *C. elegans* genes, much less those of genes expressed in the germ line. Neither provides any evidence that there were any known structural characteristic of 3' UTRs of *C. elegans* genes expressed in the germ line that would distinguish them as a genus from other 3' UTRs not embraced by the claims.

Allowable Subject Matter

Claims 136-138 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633